## Exhibit 7 Part 3

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., Master Civil Action No. 01-12257-PBS, Subcategory Case No. 06-11337

Exhibit to the December 21, 2009 Declaration of Sarah L. Reid in Support of Dey's Opposition to Plaintiffs' Motion for Partial Summary Judgment

will enable us to direct program memoranda, data specifications, error inquiries and informational materials to the proper addresses and individuals within your organization. This enclosure must be completed and returned for each labeler code portion of the NDC number issued to your company by the Food and Drug Administration.

Subsequent to this initial submittal, changes to contact names, addresses and telephone numbers should be submitted to HCFA as they occur. This information should be submitted on letterhead stationery, signed by your authorized representative and forwarded to the HCFA address under the "Completing the Rebate" section of this cover letter.

- Enclosure C entitled, "Manufacturers Data Definitions", 2. contains the definitions of the data elements that are required for each of your drugs identified by an NDC number. Included in this enclosure is the format to be used for paper submittals and the record layout for telecommunications. Detailed specifications for telecommunications or diskette will be sent to your organization as soon as we process your signed agreement containing the data submittal option chosen by your organization. If you do not have the capability to submit the required information on diskette or telecommunications and have 5 or fewer drug products you will be allowed to submit paper documentation for the first 2 quarters covered by the rebate agreement. If you are in this category please make arrangements for conversion to diskette or telecommunications at your earliest opportunity.
- Enclosure D, entitled "Medicaid Drug Rebate Data Elements Records from HCFA to State Agencies Quarterly", lists those data elements which will be sent to the States by HCFA.
- 4. Enclosure E, entitled "Medicaid Drug Data Elements Record from State Agencies to HCFA and Manufacturers Quarterly", describes those data elements which must be sent by the States to manufacturers and to HCFA for each drug product identified by an NDC number.

## STATE REQUIREMENTS

Because the rebats agreement is between HCFA and the manufacturers, it does not address a number of requirements that the State Medicaid programs must meet or how HCFA plans to implement these requirements.

It will be important that State Medicaid programs maintain a database by manufacturer to reliably produce data on the quantity of the drugs dispensed and for which payment was made. HCFA will monitor that performance and where problems are noted (including those brought to our attention by you), will work to bring the State(s) into compliance with these requirements.

The validity of the Medicaid utilization information is also of importance to HCFA. We have required that State Medicaid Agencies report their utilization data by full NDC number, except where States do not have such a capability. Where a State does not currently have the capability to provide full NDC numbers, we will mandate that it use full numbers starting March 1, 1992. We are also seriously considering requiring States to report their claims paid by ZIP code (or if unable to do so, to provide a claims history file) starting no later than March 1, 1993.

State Medicaid Agencies will receive information on the "unit rebate amount" from HCFA. This will tell them what rebate amount to expect from you per unit (tablet, gram, ml, etc.) of drug. Some States-may use this to generate an invoice of the total rebate expected from you. For Single source and innovator multiple source drugs, the unit rebate amount will include any additional rebate due because the average manufacturer price increase of the drugs exceeded the CFI-U.

Finally, HCFA will monitor the timeliness of the rebate payments through the States. Late manufacturer rebate payments received by the State will be noted and actions, as provided by the Act, taken by HCFA.

## COMPLETING THE REBATE AGREEMENT

Please note this is a standard rebate agreement being offered to all manufacturers. You may not alter it, medify it, or otherwise change it. I have signed this agreement on behalf of HCFA. The agreement that is part of this package must be the one that is signed by you and returned. If these conditions are not met, we will return the agreement to you and request that you meet these conditions. The date that the rebate agreement is entered into will be the date of the postmark for the agreement returned to us properly completed and executed.

Following this cover note is additional information presented in a question and answer format (anclosure F).

HCFA has also established a hotline telephone number if you have further questions or if you would like the CPI-U numbers. That number is (301) 966-3249 and will be open 8:00 e.m.-5:00 p.m. Monday-Friday except Federal holidays.